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Coronavirus outbreak

From Brisbane to Puerto Rico: how a \$38m Covid-19 test kit deal turned sour

The obscure Australian company Promedical said it could supply kits desperately needed by the US territory. But its claims did not stand up to scrutiny

Ben Smee and **Christopher Knaus**

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Paramedic ambulance drivers in San Juan take parxhibito24st agagep2en6 144o's management of the coronavirus crisis. Photograph: Thais Llorca/EPA

Halfway across the world, Puerto Rican scientist Daniel Colón-Ramos watched Australian breakfast television with a growing sense of dread.

The host of Channel Nine's Today Show, Karl Stefanovic, was interviewing a doctor from a small Brisbane company, Promedical Equipment, who was making extraordinary claims about its ability to supply millions of Covid-19 antibody tests to Australia each week.

Promedical, virtually unheard of before the pandemic, was of sudden and immense interest to Colón-Ramos, a Yale University cell biologist volunteering with scientific colleagues to help improve Puerto Rico's pandemic response.



Australian firm under TGA investigation says it is making coronavirus tests, despite having no approval or expertise

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live."

The company had made promises to a strange cast of intermediaries working for the Puerto Rican government, saying it was able to quickly supply large quantities of desperately needed Covid-19 antibody tests as part of a US\$38m (A\$59m) deal.

"I watched this video and this guy is being interviewed in front of a garbage truck, there was a garbage truck behind him, backing up," Colón-Ramos tells Guardian Australia.

"I became worried about who was supplying these important tests to Puerto Rico, where my parents and many loved ones



A lab technician uses a rapid test to examine a blood sample taken in San Juan, Puerto Rico. Photograph: Ricardo Arduengo/AFP via Getty Images

The US\$38m deal was Puerto Rico's single biggest expenditure on testing.

It collapsed.

Promedical was never paid, no final agreement was reached, and the tests never materialised in San Juan. Puerto Rico — where testing and contact tracing was the primary strategy against Covid-19 — is now in a testing crisis.

The deal's collapse, while unlikely to have been Promedical's fault, has prompted global scrutiny of the claims the company was making at the height of the pandemic.

Leaked emails show it had promised Puerto Rico's intermediaries it could send large shipments of Covid-19 testing "on the first available lift flight" as soon as it was paid.

At the time, it held only a small batch of testing kits of unknown provenance in its Brisbane warehouse.

After lengthy investigation and due diligence, I have decided to distance myself from Promedical Bradley Mayo

Its promises were findfally based on a deal to resell testing kits made by a reputable Chinese manufacturer, which collapsed without Promedical receiving the devices. When that broke down, Promedical decided to start manufacturing its own Covid-19 tests, Guardian Australia has learned.

Promedical, which is headed by a convicted rapist, has no prior experience in the complex business of manufacturing diagnostic devices.

The company is better known for selling erectile dysfunction, vaginal rejuvenation, massage and cryotherapy machines, and similar promises to supply the Australia government with 500,000 testing kits have not been fulfilled.

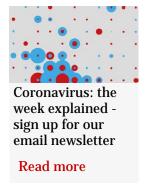
All the while, Promedical's website continued to falsely claim it had regulatory approval from Australia and the US for the devices it was selling.

The man managing Promedical's exports and logistics, Bradley Mayo, has now walked away from the company, saying he is uncomfortable with what he has learned about its practices.

"In these unprecedented and extremely challenging times, the medical supply chain industry is volatile at best, with many opportunists who aim to use this time of crisis to ... enrich themselves," he wrote in an email obtained by Guardian Australia.

"After lengthy investigation and due diligence, I have decided to distance myself from Promedical."

The Puerto Rico deal



In Puerto Rico, a US territory where disaster after disaster has made citizens vulnerable and social distancing difficult, comprehensive testing was its government's only viable strategy to counter Covid-19.

The proposed US\$38m transaction was the strategy's centrepiece.

It was relying on an unusual band of characters to pull it off.

The sale was brokered by the owner of a New Jersey supplement company, and the tests were to be paid for by a tiny construction firm in San Juan with ties to a former government of the hipit 21 Page 5 of 14

The arrangement shocked experts like Colón-Ramos.

The government had placed huge reliance on antibody tests, instead of the ribonucleic acid testing favoured by much of the world, and the construction company given responsibility for finding them, Apex General Contractors, had no obvious experience in medical devices.

On 26 March, the government awarded a "fast track" contract to Apex after representations by Juan Maldonado de Jesus, a former director of the territory's maritime authority. Local media reports suggest Maldonado submitted a brochure about the Promedical-branded tests and promised they could arrive in San Juan within five days.



A drive-through testing site in San Juan. Photograph: Ricardo Arduengo/AFP via Getty Images

Promedical subsequently told the Associated Press it had not been in conversation or entered into a contract with Apex.

But emails reviewed by Guardian Australia, firstage 6 of 14 revealed by the local newspaper NotiCel, show Promedical told Maldonado it could dispatch 1m tests soon after payment was made.

"I just wanted to confirm for safety and financial purposes, given the size of the order, that Promedical was in fact working with our order, procured through your North American distributor," Maldonado wrote to Mayo from Promedical on 30 March.



Australian government sought to buy 500,000 Covid-19 test kits from company now under investigation

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Mayo responded: "It is extremely hard to hold unpaid stock as we are producing for governments departments around the world.

"Once remittance is received we treat all clients orders with urgency and priority.

"Your order will be booked on the first available lift flight by our partner DHL after payment received."

Promedical: from cryotherapy to pandemic testing

The Brisbane company's main business before the pandemic was selling fatfreezing technology, ultrasound vaginal rejuvenation, erectile dysfunction machines and "biohacking" devices.

Its founder and chief executive, Neran de Silva, is a convicted rapist and has made claims to be a doctor through his previous business, Cryo Australia.

He claims on his LinkedIn page to have medical qualifications from the University of Queensland and Griffith University but neither has any record of him in their online graduate verification systems.

A spokeswoman for Promedical said De Silva did not claim to be a "practicing medical doctor".



Brisbane, where Promedical Equipment is based Photograph: Darren England/AAP

Promedical has no diagnostic experience. The only approved Australian manufacturer of Covid-19 tests is AusDiagnostics Pty Ltd, a company headed by the Cambridge-educated molecular biologist and immunologist Keith Stanley. It has offices in London. Dallas and Auckland.

For Promedical and its chief executive, the pandemic presented a much-needed business opportunity.

Just months earlier, De Silva had lost his final appeal in Australia's high court against a rape conviction, after years in court unsuccessfully battling allegations he sexually assaulted a woman in the Brisbane suburb of Fortitude Valley in 2016.

His name and affairs had been thrown into the spotlight when Guardian Australia revealed that the Australian politician Stuart Robert, now a cabinet minister, had invested in De Silva's alternative health company Cryo Australia, which treated ailments using a human-sized cooler.

When Cryo Australia collapsed last year it owed more than \$1.4m, liquidators said in a report to creditors, including \$410,000 to a company linked to Robert and his business partner.

'We assumed it was authorised to sell'

In March Promedical gained regulatory approval to act as a reseller of Covid-19 rapid tests made by a well-regarded manufacturer in China, Guangzhou Wondfo Biotech.

Promedical also said it sent sample kits to us (it even sent us a tracking number), but we never received any kits
Tyler Brossart, 501
Nutrition

The approval connected the company to people across the globe who were also keen to involve themselves in the coronavirus response. A company from New Jersey, 501 Nutrition, entered into an arrangement with Promedical in March to find US-based buyers for large quantities of tests supplied by the Australian company.

Information supplied to Guardian Australia by 501 Nutrition's attorney indicates that Promedical had sent glossy brochures about its own branded test kits, but its

documentation – sent as evidence it had approval to sell tests – related to those manufactured by Wondfo.

"Promedical represented that it manufactured the test kits," says Tyler Brossart, the 501 Nutrition company president.

"Its website and documentation from the
Australian Government approving the device
supported its representation. Based on
Promedical's representation that it was the
manufacturer, we assumed it was authorised to sell and export the device.

"We had ongoing negotiations with them, mostly trying to verify if they had product, and what exactly it was. We attempted on multiple occasions to have an independent third party verify the goods, but were unable to do so. Promedical also said it sent sample kits to us (it even sent us a tracking number), but we never received any kits."

Promedical disputes the description of its dealings with 501. It said 501 had made the initial approach on 28 March.



After a series of disasters, Puerto Ricans are particularly vulnerable to coronavirus. Photograph: Ricardo Arduengo/AFP via Getty Images

"Promedical issued 501 Nutrition an invoice on 31 March 2020 for the requested number of COVID-19 Rapid Test Kits [for the Puerto Rico deal], in line with the company's standard ordering process. The order was never finalised by 501 Nutrition, nor was the invoice ever paid.

"As a result, the order was terminated and Promedical did not send any product to the company."

Most of the parties involved in the deal have sought to blame one another for its collapse. But it appears that the reason payment was never made, and the tests were never sent, is that a bank in Puerto Rico intervened.

The Oriental Bank placed a US\$19m deposit from the government to Apex into escrow and froze the Puerto Rican company's account, because it had security concerns about the deal. A few days later the government cancelled the Apex contract because the tests had not materialised when they were supposed to.

A shifting narrative

Last week, when Guardian Australia approached Promedical about false public claims that the company had various approvals, it said tests were being delivered to it by an "Australian supplier" it refused to name.

This week, when the Guardian obtained evidence that it had been importing the test's main chemical reagent from South Korea, the company said it "works with a number of different suppliers" but that Promedical was the ultimate manufacturer and that the "final test" was Australian.



Investigation launched into coronavirus test claims by Australian firm run by convicted rapist

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Asked whether Promedical was equipped to be making Covid-19 testing devices, given its lack of experience, a spokeswoman compared its actions to other industries pivoting their production during the pandemic.

"From aeronautical companies manufacturing ventilators and major fashion houses producing face masks, to distilleries producing hand sanitiser; there is an incredibly strong drive to support local communities wherever possible," she said.

The company is not sanctioned to supply tests in Australia but is seeking regulatory approval for its own devices from the Therapeutic Goods Administration in Australia and from the Food and Drug Administration in the US.

It has defended its attempts to sell the tests overseas based on an export-only listing on the Australian Register of Therapeutic Goods.

But all applications for export listing are placed on the register. An additional export certificate — which Promedical does not have — is required to send medical devices to most countries, excluding the US.

The Therapeutic Goods Administration said: "At this stage, the TGA is yet to issue an export-only certificate to Promedical. A TGA issued export certificate is required by most importing countries.

They were preying on the most vulnerable time in our history to make a dime Daniel Colón-Ramos, scientist "The TGA can and will take action in relation to any reports of potential non-compliance related to any devices included in the ARTG, including export-only devices."

A company spokeswoman said Promedical "works closely with all regulatory bodies in Australia and overseas, including the TGA, to make a positive

impact and provide high quality product to assist in managing the current Covid-19 health crisis".

Mayo said he had managed Promedical's logistics but had not been involved in the procurement of components or regulatory approvals.

When told the TGA was investigating Promedical, and that it did not have export certificates necessary to send medical devices to most countries, Mayo said he was "just dumbfounded".

"I've got nothing to hide, I'm just doing the logistical side of it," he said.

Profiting from the pandemic

Promedical's interactions in Puerto Rico have brought into focus the at-times murky business of the pandemic.



A closed commercial area in San Juan. Photograph: Ricardo Arduengo/AFP via Getty Images

Covid-19 rapid test kits such as those marketed by Promedical can retail for \$40 a test. The Puerto Rico government's deal was to buy them for about US\$38 from Apex.

The local newspaper El Nuevo Día reported that the same tests were normally available on the international market for less than US\$10.

The public health emergency has created an overwhelming demand for tests and at the same time forced regulators to relax usually stringent reviews of new products and issue emergency approvals.

But before the tests get to where they are needed, in some circumstances up to six companies are taking a cut. These include manufacturers, exporters, agents, freight firms and suppliers.

Nowhere is the impact of this convoluted wheeling and dealing more stark than in Puerto Rico. The island now has the lowest testing rate of any US state or territory.

The Puerto Rico legislature is now holding a formal inquiry into the saga. Colón-Ramos says Puerto Ricans are seething.

"They were preying on the most vulnerable time in our history to make a dime," he says. "It's just unforgivable."

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